

10/507293

DT09 Rec'd PCT/PTO 09 SEP 2004

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application : DAVID B. DUNGER, et al.
Serial No. :
Filed : HEREWITH
For : TREATMENT OF TYPE I DIABETES
MELLITUS
Examiner :
Attorney Docket : 102657-102
Group Art Unit :
Confirmation No. :
Customer No. : 27267

I hereby certify that this correspondence is being deposited with
the United States Postal Service as first class mail in an
envelope addressed to: Commissioner for Patents, P. O. Box 1450,
Alexandria, VA 22313-1450 on 9 SEPT 2004.

By

Todd E. Garabedian
Todd E. Garabedian, Ph.D.
Registration No. 39,197
Attorney for Applicant(s)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.56, the Examiner is respectfully
requested to consider the references cited on attached Form PTO-
1449. A copy of each reference has been previously submitted
from the International Bureau. It is respectfully requested that
the information be expressly considered during the prosecution of
this application, and that the reference(s) be made of record
therein and appear among the "References Cited" on any patent to
issue therefrom.

- [X] 1. This Information Disclosure Statement is being filed
within three months of the U. S. filing date OR before the
mailing date of a first Office Action on the merits. No
certification or fee is required.

- [] 2. This Information Disclosure Statement is being filed more than three months after the U. S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- [] a. Each item of information contained on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. \$1.97(e)(1); and no fee is required under 37 C.F.R. \$1.17(p).
- [] b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. \$1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. \$1.97(e)(2); and no fee is required under 37 C.F.R. \$1.17(p).
- [] Please charge Deposit Account No. 23-1665 in the amount of \$240.00 in payment of the fee under 37 C.F.R. \$1.17(p). Two additional copies of this Information Disclosure Statement are enclosed.
- [] A check in the amount of \$240.00 is attached hereto in payment of the fee under 37 C.F.R. \$1.17(p).
- [] 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered.
- [] a. Each item of information contained on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. \$1.97(e)(1).

10/507293

Page 3 of 3

- [] b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e) (2).
- [] Please charge Deposit Account No. 23-1665 in the amount of \$130.00 in payment of the fee under 37 C.F.R. §1.17(i) (1). Two additional copies of this Information Disclosure Statement are enclosed.
- [] A check in the amount of \$130.00 is attached hereto in payment of the fee under 37 C.F.R. §1.17(i) (1).

The undersigned represents that the closest art of which he is presently aware has been cited herein and understands that this statement shall not be construed as a representation that no better art exists or that a thorough patentability search has been made.

The undersigned further represents that the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

Respectfully submitted,

DAVID B. DUNGER ET AL.

Date: 9 SEPT 2004

By: Todd E. Garabedian
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By Todd E. Garabedian
Todd E. Garabedian, Ph.D.
Registration No. 39,197
Attorney for Applicant(s)

INFORMATION DISCLOSURE LETTER

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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The undersigned represents that the closest art of which he
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The undersigned further represents that the filing of this
Information Disclosure Statement shall not be construed to be an
admission that the information cited in the Statement is, or is
considered to be, material to patentability as defined in 37
C.F.R. § 1.56(b).

1. WO 96 40203 (Ohio University Edison Biotech). 19
December 1996.

2. WO 95 35110 (Ergo Science Inc.; Univ, Louisiana State)
28 December 1995.
3. Goffin V. et al., "Pegvisomant Pharmacia," Current
Opinion in Investigational Drugs, Pharmapress, US,
vol. 3, no. 5, 2002, pgs 752-757.
4. Atiea, J.A. et al., "Early Morning Hyperglycemia in
Insulin-Dependent Diabetes: Acute and Sustained
Effects of Cholinergic Blockade," Jour. of Clin.
Endocrin. and Metabolism, vol. 69, no. 2, 1989 pgs.
390-395.
5. Aman, J. et al., "Reduced growth hormone secretion
improves insulin sensitivity in adolescent girls with
type 1 diabetes," Acta Paediatrica, vol. 85, no.1,
1996, pages 31-37.

Applicants submit that copies of the above-cited references
have been previously submitted to the United States Patent and
Trademark Office by the International Bureau.

If the Examiner has any questions or feels that a
discussion with Applicants' representative would expedite
prosecution, the Examiner is invited and encouraged to contact
Applicants' undersigned representative at the telephone number
listed below.

Respectfully submitted,

David B. Dunger et al.

Date: 9 SEPT 2004

By:

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| INFORMATION DISCLOSURE | ATTY. DOCKET NO. 102657-102 | SERIAL NO. 10/507293 |
| | APPLICANT: DAVID B. DUNGER ET AL. | |
| | FILING DATE: HEREWITH | GROUP: |

U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | DOCUMENT NO. | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPR. |
|-------------------|--------------|------|------|-------|----------|----------------------|
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FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
|-------------------|--------------|----------|---------|-------|----------|-----------------------|
| | 96 40203 | 12/19/96 | WO | | | |
| | 95 35110 | 12/28/95 | WO | | | |
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OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

Goffin V. et al., "Pegvisomant Pharmacia," Current Opinion in Investigational Drugs, Pharmapress, US, vol. 3, no. 5, 2002, pgs 752-757.

Atiea, J.A. et al., "Early Morning Hyperglycemia in Insulin-Dependent Diabetes: Acute and Sustained Effects of Cholinergic Blockade," Jour. of Clin. Endocrin. and Metabolism, vol. 69, no. 2, 1989 pgs. 390-395.

Aman, J. et al., "Reduced growth hormone secretion improves insulin sensitivity in adolescent girls with type 1 diabetes," Acta Paediatrica, vol. 85, no.1, 1996, pages 31-37.

EXAMINER:

DATE CONSIDERED:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include c/opy of this form with next communication to applicant.